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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,054	10/23/2003	Peter D. Costantino	1129407-0007	7277
7470 7590 03/13/2007 WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036			EXAMINER SEVERSON, RYAN J	
			ART UNIT	PAPER NUMBER
			3731	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/13/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/692,054	Applicant(s) COSTANTINO ET AL.	
	Examiner Ryan Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25-62 is/are pending in the application.
- 4a) Of the above claim(s) 31, 44-49, 61 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-30, 32-43 and 50-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>20070307</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/15/05, 7/27/06</u> . | 6) <input type="checkbox"/> Other: _____.  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of group 1, species 2 and bowl configuration as in figure 12 in the reply filed on 21 December 2006 is acknowledged. The traversal is on the ground(s) that all of the claims are related to the same inventive concept and therefore should be examined together. This is not found persuasive because burden has been established in the previous restriction/election requirement. The allegation that claims are related to the same concept in no way precludes the examiner from making a proper restriction. The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 31, 44-49, 61, and 62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 21 December 2006.

### *Drawings*

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 16 (page 14, line 12) and 21 (page 14, line 25). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should

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include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. The disclosure is objected to because the "Brief Description of the Drawings" section is replete with errors. There appears to be multiple mistakes regarding which drawings each brief description is referring to. It is suggested applicant carefully review each brief description with respect to each figure to ensure accuracy thereof. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "said biodurable reticulated elastomeric matrix" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 25-30, 32-43, 50, and 58-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilson (5,904,703).**

8. Regarding claims 25, 28, 32, 40, and 41, Gilson discloses a treatment device with two expandable implants (4 and 5) being expandable between a first small configuration (see column 5, lines 16-18) and a second large configuration (see column 5, lines 21-23). The implants provide support to a portion of the internal wall (see column 4, line 67 through column 5, line 2) and are made of expandable polymeric foam (see column 4, lines 30-33). The implant is first compressed before implantation and then expanded to a substantially relaxed position upon release of the restraining means (i.e. deployment from the delivery catheter).

9. Regarding claims 26, 27, 34, and 60, as applicant discloses on page 27, lines 12-15 of the disclosure in the present application, "The porous biodurable elastomeric matrix is considered to be reticulated because its microstructure or the interior structure comprises inter-connected open pores bounded by configuration of the struts and intersections that constitute the solid structure." Gilson discloses a porous matrix (see figures 1a-3) and therefore also is interpreted to comprise a reticulated elastomeric

matrix. The device is biodurable because it is made from polymer and does not dissolve or degrade over time.

10. Regarding claims 29 and 58, the device further includes a biodurable member (11, see figure 3). The member is biodurable because it does not degrade or dissolve over time. This biodurable member is radiopaque (see column 4, lines 44-47) and therefore can be seen properly located and deployed using conventional imaging techniques.

11. Regarding claims 30, 50, and 59, the implant has a fluidic path there through (see figures 1a-3) that is considered a continuous interconnected void because the void (or open area) extends entirely through the body without interruption.

12. Regarding claim 33, Gilson discloses a projection portion (7, see figure 2) that is in place to allow the surgeon to grasp the device (see column 5, lines 6-10).

13. Regarding claims 35-39, Gilson shows in figure 18 a device with an inserted arm portion (81) that is more rigid than the foam portion yet is still flexible (see column 6, lines 39-44). Since the arms are foldable, they are considered bendable. The arms are strut-like and perform a support function. The struts can be considered support rods because they are thin and elongated thereby providing support.

14. Regarding claim 42, the implant has an elongated configuration in both the sense that the strut arms as described above are elongated and the neck portion (6) that connects the two implants (4 and 5) is also elongated.

15. Regarding claim 43, the elongated configuration of the neck is round in cross-section (see 1a).

***Claim Rejections - 35 USC § 103***

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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19. **Claims 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson (5,904,703) as applied to claim 25 above, and further in view of Thomson (2002/0018884).** Gilson does not disclose the polymeric foam has a pore density between 14 and 60 pores per centimeter, more preferably between 16 and 32 pores per centimeter.

20. It is noted that these numbers, when converted into the more conventional "pores per linear inch" unit are in the ranges of about 35 to 150, more preferably 40-80 pores per linear inch. It is unclear to the examiner why applicant has used the "pores per linear inch" unit in the disclosure (see page 30, lines 16-21) yet converted these ranges into their metric equivalents in the claims.

21. Attention is drawn to Thomson reference, which teaches polymeric foam composites can have a pore density that varies, but cites an example of 40 pores per linear inch (see Table 1 in paragraph 73), to vary the degree and rate of expansion of the foam. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the foam of Gilson with a pore density of 40 pores per linear inch, as taught by Thomson, to vary the degree and rate of expansion of the foam.

22. **Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson (5,904,703) as applied to claim 25 above, and further in view of Spaans et al. (6,784,273).** Gilson does not disclose the foam is polyurethane with a polycarbonate polyol component and an isocyanate component. Attention is drawn to Spaans et al. reference, which teaches a polymeric foam for implants (see column 1,



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lines 65-67) may be polyurethane (see title) with an isocyanate component (see column 1, lines 56-59) and a polycarbonate component (see column 2, lines 49-54) to provide a device that has good mechanical properties but is lightweight and flexible. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the polymeric foam implant of Gilson with polyurethane having isocyanate and polycarbonate components, as taught by Spaans et al., to provide a device that has good mechanical properties but is lightweight and flexible.

23. **Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilson (5,904,703) as applied to claim 25 above, and further in view of Slaikeu et al. (6,231,590).** Gilson does not disclose the foam further includes growth factors or elastin. Attention is drawn to Slaikeu et al. reference, which teaches an implant may include elastin and/or growth factors (see column 7, lines 15-21) to promote cellular ingrowth between the implant site and the implant itself. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include elastin and growth factors in the implant of Gilson, as taught by Slaikeu et al., to promote cellular ingrowth between the implant site and the implant itself.

### ***Conclusion***


24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 6,723,108 to Jones et al. and 6,165,193 to Greene, Jr. et al. also disclose the expandable polymeric foam substantially as claimed.

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25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Ryan Severson  
March 7, 2007

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**

12/11/07